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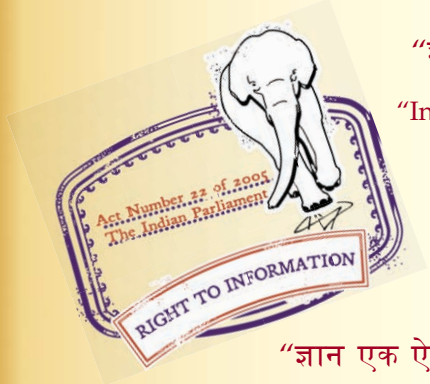
IS 6395 (1989): Thoracic Surgery Instruments - Clamps, Auricle, Crafoord's Pattern [MHD 6: Thoracic and Cardiovascular Surgery Instruments]



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"Knowledge is such a treasure which cannot be stolen"

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IS 6395 : 1989

Indian Standard (Reaffirmed 2005)

THORACIC SURGERY INSTRUMENTS — CLAMPS, AURICLE, CRAFOORD'S PATTERN — SPECIFICATION

(First Revision)

भारतीय मानक

वक्ष शल्यक्रिया उपकरण — आलिन्द क्लैम्प, क्रेफूर्ड नमूना — विशिष्टि

(पहला पुनरीक्षण)

UDC 615·472·2 : 617·54

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110 002

April 1990 Price Group 2

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards on 19 May 1989, after the draft finalized by the Thoracic and Cardiovascular Surgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first issued in 1971. In this revision, tolerances on various dimensions have been specified; load closure, gripping and drop tests and an additional test for flexibility have been incorporated and the requirements for surface condition, marking and packing have been modified. Besides, a recommended sampling plan has been added.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

THORACIC SURGERY INSTRUMENTS — CLAMPS, AURICLE, CRAFOORD'S PATTERN — SPECIFICATION

(First Revision)

1 SCOPE

This standard prescribes requirements and tests for Crafoord's pattern auricle clamps used in thoracic surgery.

2 REFERENCES

The Indian Standards listed below are necessary adjuncts to this standard:

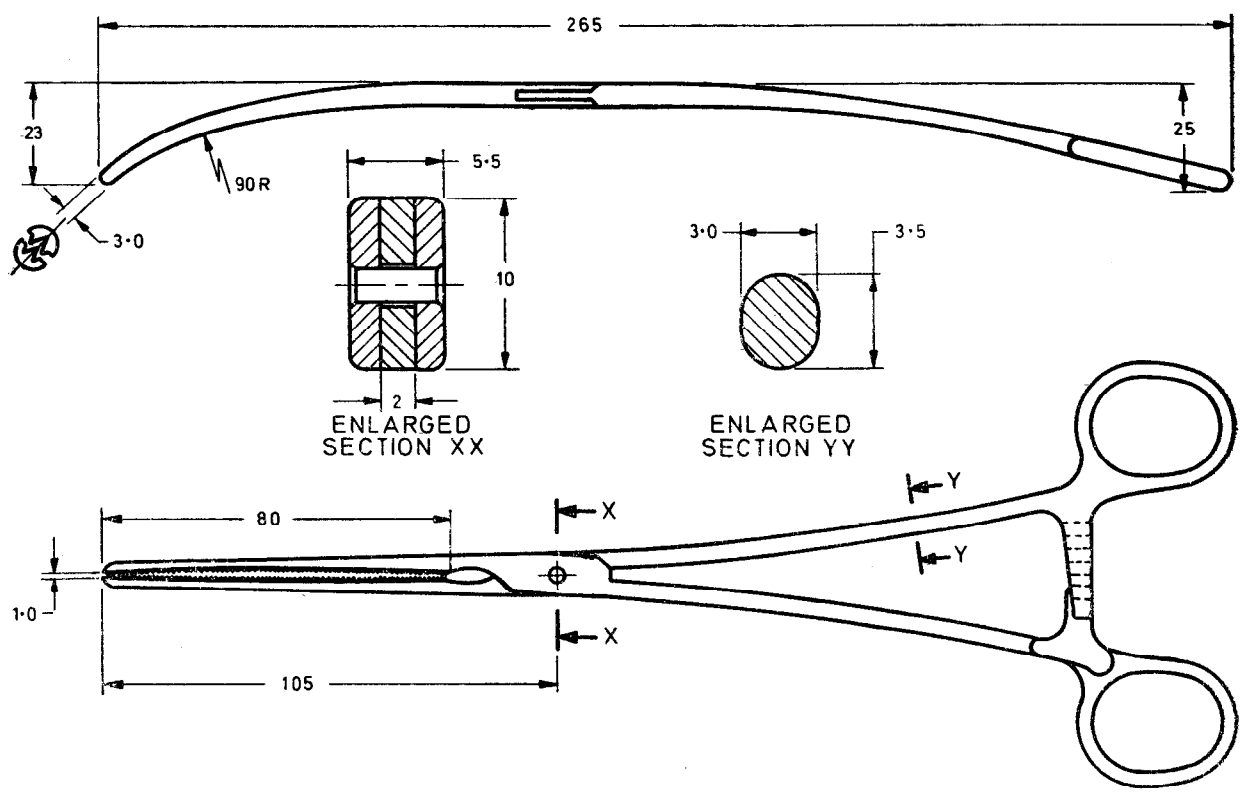
IS No.	*Title*
IS 1501 (Part 1) : 1984	Method for Vickers hardness test for metallic materials: Part 1 HV 5 to HV 100 (*second revision*)
IS 3642 : 1978	General requirements for surgical instruments (*first revision*)
IS 4905 : 1968	Methods for random sampling
IS 6528 : 1972	Stainless steel wire
IS 6603 : 1972	Stainless steel bars and flats
IS 7531 : 1975	Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments

3 MATERIAL

The instrument shall be made of stainless steel conforming to Designation 20Cr13 or 30Cr13 of IS 6603 : 1972.

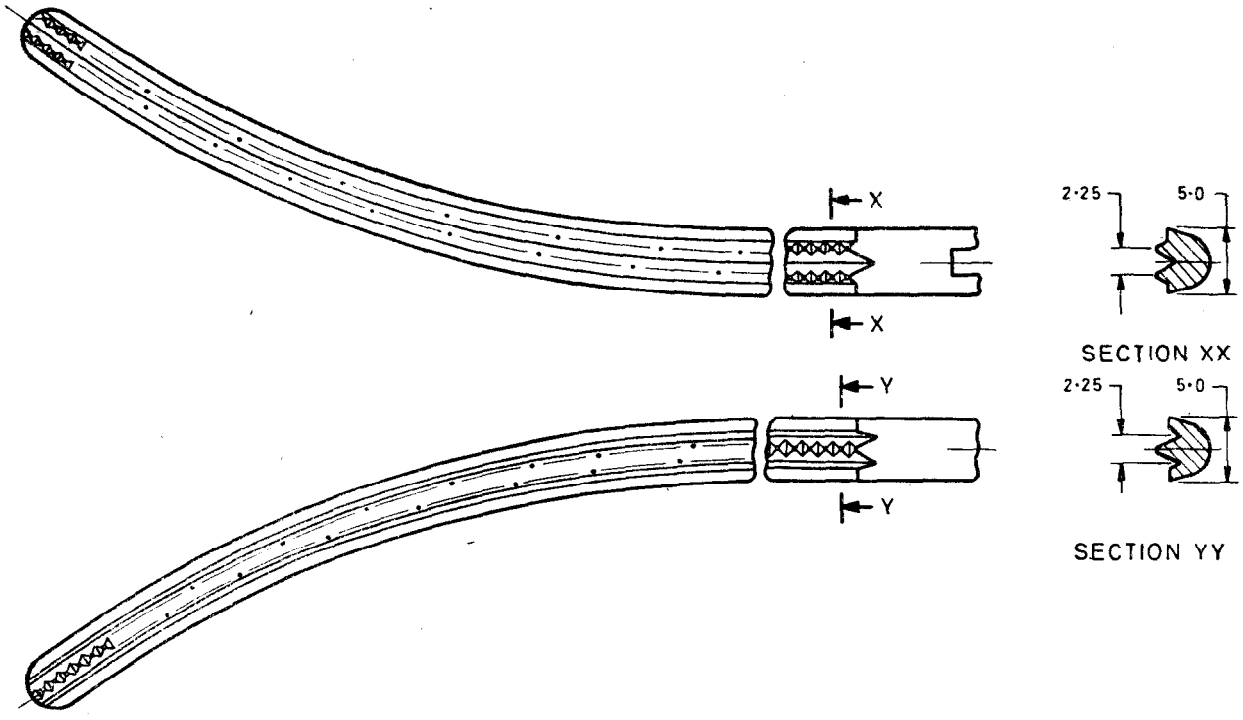
4 SHAPE AND DIMENSIONS

4.1 The shape and dimensions of the instrument shall be as shown in Fig. 1 to 3.



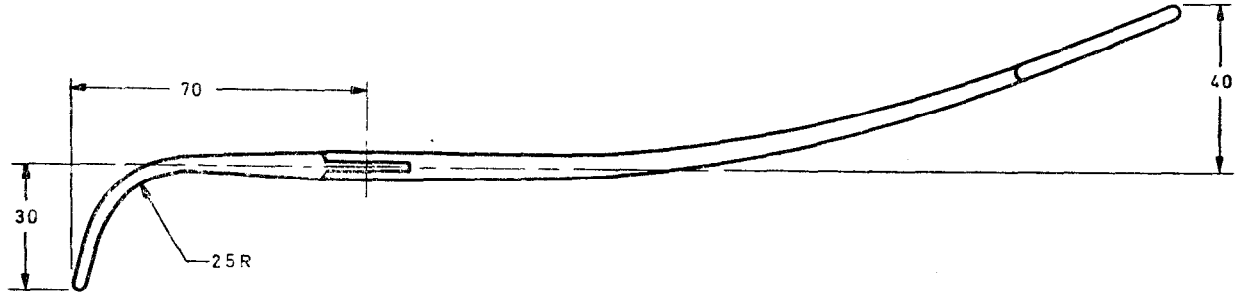
All dimensions in millimetres.

FIG. 1 CLAMP, AURICLE, CRAFOORD'S PATTERN (SLIGHTLY CURVED)

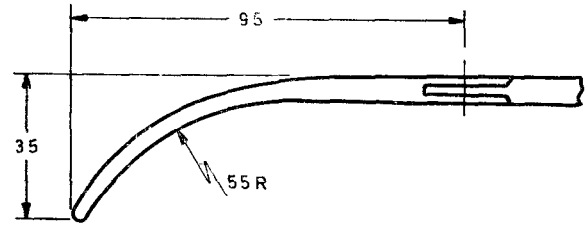


All dimensions in millimetres.

FIG. 2 ENLARGED DETAIL OF JAWS



DEEP CURVED



CURVED

All dimensions in millimetres.

FIG. 3 CLAMP, AURICLE, CRAFOORD'S PATTERN (CURVED AND DEEP CURVED)

4.2 Tolerances

Tolerances on linear dimensions shall be as given below:

± 0·05 mm on dimensions up to 2·0 mm

± 0·1 mm on dimensions above 2·0 mm and up to 5·0 mm

± 0·2 mm on dimensions above 5·0 mm and up to 20·0 mm

± 0·5 mm on dimensions above 20·0 mm and up to 50·0 mm

± 1·0 mm on dimensions above 50·0 mm and up to 100·0 mm

± 2·0 mm on dimensions above 100·0 mm.

4.2.1 The two halves of the instrument shall, however, not differ at any dimension and shall match each other perfectly.

5 MASS

The mass of the instrument shall be 65 to 80 g.

6 HEAT TREATMENT

6.1 The instruments shall be uniformly hardened and tempered to a hardness of 400 HV to 460 HV, when tested in accordance with IS 1501 (Part 1) : 1984.

6.2 Mating surfaces on the same instrument, such as opposite jaws and shanks, shall not vary in hardness by more than 40 HV.

7 WORKMANSHIP

7.1 The opening and closing of the jaws shall be smooth and jerk free.

7.2 The joint shall conform to the relevant requirements of Section 2 of IS 3642 : 1978.

7.3 The serrations on the jaws shall be longitudinal with non-truncated 60° profile and shall conform to relevant requirements of Section 1 of IS 3642 : 1978 except that the test for engagement of the jaws shall be as in **9.1**.

7.4 The ratchet teeth shall be with combination of 1 in 7 and shall conform to Section 3 of IS 3642 : 1978.

7.5 The finger loops shall be in accordance with the relevant requirements of Section 5 of IS 3642 : 1978.

7.6 There shall be no sharp edges.

8 SURFACE CONDITION

8.1 General

All surfaces shall be free from pores, crevices and grinding marks. The instruments shall be free from residual scale, acid, grease grinding and polishing materials. Compliance with these requirements shall be checked by visual inspection.

8.2 Surface Finish

The surface finish of the instrument shall be reflection-reducing, for example satin finish, matt black finish.

NOTE — The satin finish should be achieved by an appropriate procedure, such as grinding, brushing, electropolishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth and it should reduce glare.

8.3 Passivation and Final Treatment

The instruments shall be treated by a suitable passivation process, for example by electropolishing or by treatment with 10 percent (*v/v*) nitric acid solution for not less than 30 minutes at a temperature not less than 10°C and not exceeding 60°C. The instruments shall then be rinsed in water and dried in hot air.

NOTE — If the joint is lubricated, the lubricant should be non-corrosive and suitable for medical application according to the Indian Pharmacopoeia.

9 TESTS

9.1 Test for Engagement of Jaws

When the first step of the ratchet is engaged, the serrations shall approximate to a gap of 1 mm at the extreme end of the tip. The tip shall bite when the second step of the ratchet engages. The jaws shall fully close when the last ratchet engages. The serrations shall engage perfectly and truly.

9.2 Load Closure Test

By fixing one finger loop of the clamp in a vice, load shall be applied at the free finger loop by means of a pan or spring balance The loads at which different steps of the ratchet engage shall be noted. The load required to close the clamp on the first step of the ratchet shall be 2·5 N (250 gf approximately). For the second step the load shall be 5 N (500 gf approximately), for the third step 7·5 N (750 gf approximately), and so on.

9.3 Flexibility Test

9.3.1 Each arm of the clamp shall be fixed in a vice so that the entire arm projects above the vice. By gradual application of force on the finger loop, the arm shall be deflected by 15 mm in the same plane as that of finger loop. The arm shall not take a permanent set or break.

9.3.2 Place a stainless steel wire of 5 mm dia, conforming to Designation 04Cr18Ni10 of IS 6528 : 1972 between the tips of the instrument jaws. Fully close the instrument to the last ratchet position. Leave the instrument in this position for 3 hours at room temperature. After the test, no distortion, cracks or any other permanent set in the instrument shall be visible.

9.4 Gripping Test

A piece of fresh goat or pig aorta shall be placed between the jaws of the instrument. The instrument shall then be closed to the last ratchet position and kept under this strain for 3 hours at a temperature of 25 ± 2°C. After or during this test, no distortion, cracks or any other permanent deformation of the instrument shall be visible. The aorta shall not get crushed, pierced or damaged.

9.5 Drop Test

The instrument shall be dropped from a height of 150 cm on a concrete floor 5 times and shall then be examined visually. There shall be no damage or distortion or malfunctioning of the instrument. After this test, the clamp shall again satisfy the requirements of flexibility test.

9.6 Corrosion Resistance Test

The instruments shall be tested in accordance with IS 7531 : 1975. They shall show no sign of corrosion after the test.

10 MARKING AND PACKING

10.1 The instruments shall be legibly and indelibly marked with the manufacturer's name, initials or recognized trade-mark; the words 'stainless steel' or letters 'SS' and the country of manufacture.

10.2 Each instrument shall be wrapped in a suitable cushioning material like folded tissue paper. It shall then be put in a polyethylene bag or wrapped in wax paper. The instruments shall thereafter be packed in cartons in accordance with the current trade practice.

10.2.1 Alternatively, the instruments may be packed as agreed to between the purchaser and the supplier.

10.3 The packages shall be marked with the name and shape of the instrument; the manufacturer's name, initials or recognized trade-mark; the words 'stainless steel'; and the country of manufacture.

11 SAMPLING

The scale of sampling and criteria for conformity of the instruments to the requirements of this specification shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A.

ANNEX A

(*Clause* 11)

SAMPLING OF CLAMPS, AURICLE, CRAFOORD'S PATTERN

A-1 LOT

A-1.1 In any consignment, all the instruments of the same shape, produced from the identical material under similar conditions and having the same surface finish constitute a lot.

A-2 SAMPLING

A-2.1 The number of instruments to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

Table 1 Scale of Sampling

(*Clauses* A-2.1, A-3.1 *and* A-3.2)

Lot Size	Sample Size	Sub-Sample Size
(1)	(2)	(3)
Up to 15	2	1
16 to 50	3	1
51 to 150	5	2
151 and above	8	3

A-2.2 These instruments shall be selected from the lot at random and in order to ensure randomness of selection procedures given in IS 4905 : 1968 may be followed.

A-3 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

A-3.1 All the instruments selected according to col 1 and 2 of Table 1 shall be examined for shape and dimensions, workmanship and surface condition (visual) and tested for mass and engagement of jaws. An instrument in the sample failing to meet any of these requirements shall be considered as defective. The lot shall be considered as conforming to these requirements if no defective is found in the sample.

A-3.2 The lot having been found satisfactory according to **A-3.1** shall be further tested for other requirements. For this purpose, a sub-sample of size given in col 3 of Table 1 shall be taken. These instruments in the sub-sample may be selected from those already examined according to **A-3.1**. Each instrument in the sub-sample shall be subjected to hardness, load closure, flexibility, gripping, drop and corrosion resistance tests. The lot shall be declared as conforming to the requirements of the specification if none of the instruments in the sub-sample fails in any of these tests.

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